Manual for the Completion of CDISC Aligned NCI Standard Case Report Form (CRF) Modules

Introduction

In 2006, members of the National Cancer Institute's Center for Biomedical Informatics and Information Technology (NCI CBIIT) in conjunction with the cancer Data Standards Registry and Repository (caDSR) user community initiated a Case Report Form (CRF) harmonization activity. CRFs submitted from the community were reviewed and inventoried. The Harmonization group then reviewed all questions on the CRF and partitioned them into four categories:

- Mandatory – A data collection variable that must be on the CRF (e.g., a regulatory requirement (if applicable)).
- Conditional – A data collection variable that must be collected on the CRF for specific cases that may be dictated by local or sponsor defined business rules.
- Optional – A data collection variable that is available for use if needed. There is no regulatory or business requirement for inclusion of this element on the CRF; if the design and scientific questions posed in the study dictate the need to collect this type of data; this is the element to include on the CRF.
- Non-harmonized – A data collection variable that is, by consensus, to primarily belong to a different CRF module or is not belonging to any defined module.

A template form with modules that contain questions or variables representing data to be collected and a companion electronic CRF instruction manual was developed. These CRF modules were vetted and adopted by the caDSR stakeholder community as metadata standards.

Since the original CRFs and manuals were adopted, the Food & Drug Administration (FDA) published guidelines for submission of clinical trial study data using the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) for Investigational New Drug (IND) trials starting after December 2017. In response, NCI CBIIT has aligned the NCI Standard CRF modules with the CDISC data collection standard, Clinical Data Acquisition Standards Harmonization (CDASH) where data is expected to be submitted to FDA in SDTM format.

The instruction manual is a set of directions to guide data collection in each module template. Specific implementation instructions are not present; various groups may wish to implement the contents of a module in a variety of software applications.

The instructions include the field name, description or definition of each field, and any special formatting notes that apply to entries – such as the inclusion of full dates, use of values from a choice list only, etc. Finally, each question (or data item) is noted as Mandatory (m), Conditional (c), or Optional (o).

Off Study CDISC Aligned NCI Standard Template Module Definitions

Mapping to the CDASH:

This NCI Standard Template Form maps to the following domains in the CDASHIG v2.0 metadata table:

- DS – Disposition (v2.0)

Mapping to the SDTM:

This NCI Standard Template Form maps to the following domains in the SDTMIG v3.3 metadata table:

- DS – Disposition (v3.3)

Off Study CDISC Aligned NCI Standard Template Module Template Instructions

Field Descriptions and Instructions

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Off Study Occurrence Date (m) 7008661 DSOFSTDT	The date a patient is removed from the study represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: DSSTDAT (6384212) where DSTERM (6355980) = "Off Study" and DSSCAT (6384142) = "Off Study"; SDTM: DSSTDTC where DSTERM="OFF STUDY". Please use the DSDECOD and DSCAT = 'DISPOSITION EVENT' from CDE 7008662	DATE

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Off Study Occurrence Code (m) 7008662 DSOFTMCD	The code that represents the reason for removing the patient from the study. CDASH: DSDECOD (6414218) where DSSCAT (6384142) = "Off Study"; SDTM: If 01 PROTOCOL-DEFINED FOLLOW-UP COMPLETED, DSTERM = 'PROTOCOL-DEFINED FOLLOW-UP COMPLETED', DSDECOD = 'COMPLETED' and DSCAT = 'DISPOSITION EVENT'; If 02 Patient lost to follow-up, DSTERM = 'PATIENT LOST TO FOLLOW-UP', DSDECOD = 'LOST TO FOLLOW-UP' and DSCAT = 'DISPOSITION EVENT'; if 03 PATIENT REFUSED FOLLOW-UP, DSTERM = 'PATIENT REFUSED FOLLOW-UP', DSDECOD = 'LOST TO FOLLOW-UP' and DSCAT = 'DISPOSITION EVENT'; If 04 Death, DSTERM = 'DEATH', DSDECOD = 'DEATH' and DSCAT = 'DISPOSITION EVENT'; If 05 Adverse event/side effects/complications, DSTERM = 'ADVERSE EVENT/SIDE EFFECTS/COMPLICATIONS', DSDECOD = 'ADVERSE EVENT' (or the codelist is extensible so the sponsor/study team can use it if they choose), and DSCAT = 'DISPOSITION EVENT'; if 98 Other, please see CDE 7008663 SDTM mapping instruction	CHARACTER. Use choice list.

Field Name **(Partition Status)** **CDE ID #** **Short Name**	**Definition** **CDISC Mapping and Instruction**	**Format**
Off Study Occurrence Text (m) 7008663 DSOFTMX	The code that represents the reason for removing the patient from the study not previously listed. CDASH: DSTERM (6355980) where DSSCAT (6384142) = "Off Study"; SDTM: DSTERM = value of CDE DSOFTMX, DSDECOD = 'OTHER' (or the codelist is extensible so the sponsor/study team can use it if they choose), and DSCAT = 'DISPOSITION EVENT'	CHARACTER

Annotated CRF: Off Study CDISC Aligned NCI Standard Template

This annotated CRF is ONLY used to show CDISC mapping without consideration of the CRF layout. CDASH mapping is in **Blue**, and SDTM mapping is in **Red**.

Form Name: Off Study CDISC Aligned NCI Standard Template

Mandatary Questions

CRF Question	Value Domain
Off Study Date (7008661) **CDE Short Name:** DSOFSTDT CDASH: DSSTDAT (6384212) where DSTERM (6355980) = "Off Study" and DSSCAT (6384142) = "Off Study SDTM: DSSTDTC where DSTERM="OFF STUDY". Please use the DSDECOD and DSCAT = 'DISPOSITION EVENT' from CDE 7008662	DATE – Maximum Length = 11

CRF Question	Value Domain
Off Study Reason (7008662) **CDE Short Name:** DSOFTMCD CDASH: DSDECOD (6414218) where DSSCAT (6384142) = "Off Study" SDTM: If 01 PROTOCOL-DEFINED FOLLOW-UP COMPLETED, DSTERM = 'PROTOCOL-DEFINED FOLLOW-UP COMPLETED', DSDECOD = 'COMPLETED' and DSCAT = 'DISPOSITION EVENT'; If 02 Patient lost to follow-up, DSTERM = 'PATIENT LOST TO FOLLOW-UP', DSDECOD = 'LOST TO FOLLOW-UP' and DSCAT = 'DISPOSITION EVENT'; if 03 PATIENT REFUSED FOLLOW-UP, DSTERM = 'PATIENT REFUSED FOLLOW-UP', DSDECOD = 'LOST TO FOLLOW-UP' and DSCAT = 'DISPOSITION EVENT'; If 04 Death, DSTERM = 'DEATH', DSDECOD = 'DEATH' and DSCAT = 'DISPOSITION EVENT'; If 05 Adverse event/side effects/complications, DSTERM = 'ADVERSE EVENT/SIDE EFFECTS/COMPLICATIONS', DSDECOD = 'ADVERSE EVENT' (or the codelist is extensible so the sponsor/study team can use it if they choose), and DSCAT = 'DISPOSITION EVENT'; if 98 Other, please see CDE 7008663 SDTM mapping instruction	CHARACTER – Maximum Length = 2 ☐ 01 – PROTOCOL-DEFINED FOLLOW-UP COMPLETED ☐ 02 – Patient lost to follow-up ☐ 03 – PATIENT REFUSED FOLLOW-UP ☐ 04 – Death ☐ 05 – Adverse event/side effects/complications ☐ 98 – Other
Off Study Other, Specify (7008663) **CDE Short Name:** DSOFTMX CDASH: DSTERM (6355980) where DSSCAT (6384142) = "Off Study" SDTM: DSTERM = value of CDE DSOFTMX, DSDECOD = 'OTHER' (or the codelist is extensible so the sponsor/study team can use it if they choose), and DSCAT = 'DISPOSITION EVENT'	CHARACTER – Maximum Length = 200